APR 0 9 2014

K140047

510(k) Summary

This 510(k) summary was prepared in accordance with 21 CFR 807.92(c)

Prepared on March 20, 2014

510(k) Submitter / Holder:

Spectranetics
9965 Federal Drive
Colorado Springs, CO 80921.3617

Establishment Registration No: 3007284006

Contact:

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Subject Device

510(k) Number:	K140047
Device Trade Name:	TightRail™ Mechanical Dilator Sheath Set
Device Common Name:	Sheath
Device Class:	II
Classification Regulation:	21 CFR 870.1310
Regulation Description:	Vessel dilator for percutaneous catheterization
Product Code:	DRE
510(k) Type:	Traditional
Model Numbers:	545-509, 545-511, 545-513

Predicate Device

The TightRail Mechanical Dilator Sheath Sets were compared to the following legally marketed predicate device:

510(k) Number:	K061000 (cleared on May 10, 2006)
Manufacturer:	Cook® Medical
Trade Name:	Evolution® Mechanical Dilator Sheath Set
Device Common Name:	Sheath

Device Description

The TightRail Mechanical Dilator Sheaths are mechanical, intra-operative devices. The devices consist of a proximal handle drive mechanism with a distal dilation catheter. The sheaths are packaged with an outer support sheath. The dilator sheath is advanced, withdrawn and rotated about the lead, catheter or foreign object to be removed. Actuating the trigger on the proximal handle activates a rotary dilation mechanism sheathed at the distal terminus of the catheter. Rotation of the inner shaft is translated to axial actuation of the dilation mechanism via a cam path contained within the distal components. Actuation of the distal dilation mechanism causes dilation of tissue and fibrous attachments surrounding the object targeted for removal thereby facilitating removal of said object. The diameter sizes range from 9 French (F) to 13 F. The nominal effective length of the TightRail is 47.5 cm.

Traditional 510(k) – TightRail™ Mechanical Dilator Sheath Set

Intended and Indications for Use

The TightRail Mechanical Dilator Sheaths are intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters and foreign objects.

Technological Characteristics

The TightRail Mechanical Dilator Sheaths have similar performance characteristics as the predicate device. However, the design of the dilatation mechanism between the subject and predicate device differ. The predicate device features a single rotating outer shaft that includes an extended radial dilation blade. The cutting edges of their dilatation blade are on the exterior circumference. The subject device includes a stationary outer shaft, a rotating inner shaft, and an un-exposed dilation blade at rest. The TightRail dilatation blade extends and retracts along the inner shaft axis once the trigger is actuated. Lastly, the predicate device shaft is designed as a metal braid reinforced polymer, while the subject device shaft is composed of tri-coils. The tri-coil design increases the shaft flexibility of the subject device.

Performance Data

The following testing was conducted to validate and verify that the subject device met all specifications and was substantially equivalent to the predicate device:

Design Verification and Validation Testing

- Dimensional Verification
- Axial Loading of Tip Assembly and Outer Sheath
- Tensile and Torsional Testing on the Tri-Coil
- Simulated Use – Bench Top
- Radiopacity
- Corrosion Resistance
- Physician Simulated Use
- Simulated Distribution (Shipping and Simulated Environmental Conditing)
- Shelf Life Verification Testing (6=months)
    - Dimensional Verification
    - Axial Loading of Outer Sheath
    - Simulated Use – Bench Top
    - Package Integrity

Sterilization

- Product adoption equivalency per AAMI TIR:28-2009

Biocompatibility

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- C3a and SC5b-9 Complement Activation
- Direct Hemolysis
- Indirect Hemolysis
- *In Vivo* Thromobogenicity-Ovine Model
- Genotoxicity – Ames Test
- Material Mediated Pyrogenicity

Preclinical and Clinical Data:

Preclinical and clinical data were not required to demonstrate substantial equivalence. The design characteristics of the subject device are similar to the predicate. The design verification and validation test results demonstrated that the subject device is as safe and clinically effective as the predicate device.

Substantial Equivalence

Based on the similarities in design between the subject and predicate device, and the performance data, the TightRail is substantially equivalent to the Evolution Mechanical Dilator Sheaths (K061000).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 9, 2014

Spectranetics Corp.
Pharoah Garma
9665 Federal Drive
Colorado Springs, CO 80921 US

Re: K140047
Trade/Device Name: Tight Rail Mechanical Dilator Sheath Set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator for Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: March 10, 2014
Received: March 12, 2014

Dear Pharoah Garma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Linda J. Ricci -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140047

Device Name
TightRail™ Mechanical Dilator Sheath Set

Indications for Use *(Describe)*
The TightRail Mechanical Dilator Sheath is intended for use in patients requiring the percutaneous dilation of tissue to facilitate removal of cardiac leads, indwelling catheters and foreign objects.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Linda J. Ricci -S